ORAL ARGUMENT NOT YET SCHEDULED

No. 22-1076

United States Court of Appeals for the District of Columbia Circuit

FONTEM US, LLC,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION Respondent.

On Petition for Review of an Order of the United States Food and Drug Administration

UNOPPOSED MOTION FOR LEAVE TO FILE UNDER SEAL AND FOR LEAVE TO FILE REDACTED REPLY ON THE DOCKET

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Counsel for Petitioner Fontem US, LLC

July 5, 2022

Pursuant to Federal Rule of Appellate Procedure 27 and D.C. Circuit Rule 47.1(a), petitioner Fontem US, LLC ("Fontem") respectfully requests leave to file under seal portions of the Declaration of Shane Sgambelluri; portions of the Declaration of Carole Folmar; and the unredacted version of Fontem's Reply. The declarations from Shane Sgambelluri and Carole Folmar contain figures on Fontem's sales and revenues and the effect of the United States Food and Drug Administration's April 8, 2022 Marketing Denial Order (the "Order") on Fontem's business, all of which is confidential business information, as well as confidential communications regarding material treated as sealed by the agency.

The Reply refers to material treated as sealed by the agency, and the same material has been sealed by this Court in an order dated June 21, 2022. *See* D.C. Cir. Rule 47.1(a) ("Any portion of the record that was placed under seal . . . before an agency remains under seal in this court unless otherwise ordered. Parties and their counsel are responsible for assuring that materials under seal remain under seal and are not publicly disclosed."). Counsel for Fontem contacted counsel for FDA regarding FDA's position on the request for sealing. FDA does not oppose the request.

Dated: July 5, 2022

Respectfully submitted,

/s/ Philip J. Perry

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), I hereby certify that the foregoing motion complies with the type-volume limitations in Federal Rule of Appellate Procedure 27(d)(2)(A). According to the word count feature of Microsoft Word, the motion contains 202 words, excluding the exempted parts under Federal Rule of Appellate Procedure 32(f). This motion has been prepared using Microsoft Word 2016 in 14-point Times New Roman font.

/s/ Philip J. Perry
Philip J. Perry

CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2022, I filed the foregoing motion via the Court's CM/ECF system, which will provide electronic notice to all counsel of record.

/s/ Philip J. Perry

Philip J. Perry